



vaccinations that he received on April 20, 2011. For the reasons set forth below, the Court **DENIES** petitioner's motion for review and **SUSTAINS** the decision of the special master.

## II. FACTUAL AND PROCEDURAL BACKGROUND<sup>1</sup>

### A. Factual Background

The medical history of petitioner's grandson, Elijah McLeod ("Elijah"), is not in dispute and can be briefly summarized. Elijah, age 15, suffers from multiple sclerosis. *Hunt v. Sec'y of Health & Human Servs.*, No. 12-232V, 2015 WL 1263356, at \*1 (Fed. Cl. Spec. Mstr. Feb. 23, 2015).

In the fall of 2010, when Elijah was around eleven years old, he started using his right hand more than his left (dominant) hand. Dec. at \*4. According to subsequent medical history obtained by Elijah's treating physician, David H. Mattson, M.D., and Elijah's own testimony, Elijah also previously experienced numbness in his arm which he attributed to a sports injury. *Id.* at 7; Tr. 257. In addition, in February 2011, Elijah began having double vision. Dec. at \*2. Elijah did not seek medical attention for these conditions. *Id.* at 7.

On April 20, 2011, Elijah received booster vaccinations, including the tetanus-diphtheria acellular pertussis ("Tdap"), varicella, and meningococcal vaccines. *Id.* at \*3; Ex. 10 at 6. The next day, Elijah became ill and his mother took him to the hospital emergency room after he vomited and reported feeling dizzy and off-balance. Dec. at \*3. Elijah was assessed with having a localized reaction to a vaccination and he was not admitted to the hospital. *Id.*

On April 22, 2011, Elijah was still not feeling well and his grandmother brought him back to the hospital emergency room. *Id.* A CT scan of Elijah's brain revealed at least two areas of hypodensity and Elijah was admitted to the hospital. *Id.* A nurse's assessment from that date shows that Elijah "was acting like he had a stroke." *Id.*

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<sup>1</sup> The facts recounted in this Memorandum Opinion and Order are taken from the special master's February 23, 2015, decision in *Hunt v. Sec'y of Health & Human Servs.*, No. 12-232V, 2015 WL 1263356 (Fed. Cl. Spec. Mstr. Feb. 23, 2015) ("Dec. at \_\_\_\_"), the transcript of the hearing before the special master held on January 9, 2014 ("Tr. \_\_\_\_"), petitioner's motion for review ("Pet. Mot. at \_\_\_\_"), and respondent's response to petitioner's petition for review ("Resp. Mot. at \_\_\_\_"). Except where otherwise noted, the facts recited here are undisputed.

On April 23, 2011, pediatric neurologist Samira El-Zind, M.D. evaluated Elijah. *Id.* at \*4. According to the medical history taken by Dr. El-Zind, Elijah's mother reported concern that Elijah had been using his right (non-dominant) hand for the past seven months and that he had experienced double vision for the past two months. *Id.* Prior to performing an MRI and other tests, Dr. El-Zind's impression was that Elijah had "possible acute disseminating encephalomyelitis with [a] post-immunization reaction." *Id.* (brackets original). A subsequent MRI performed on April 23, 2011, showed large areas of abnormal signals, which the radiologist interpreted as:

[L]ikely related to acute disseminated encephalomyelitis (ADEM), seen in postvaccination settings. A demyelinating process such as multiple sclerosis is felt to be much less likely.

*Id.* A lumbar puncture also performed on that day revealed two or more oligoclonal bands in Elijah's cerebrospinal fluid ("CSF"). *Id.* Elijah began a course of intravenous steroids and physical therapy which helped his symptoms. *Id.*; Tr. at 51. Elijah was discharged from the hospital on April 29, 2011. Dec. at \*4. At that time, his diagnosis appeared to be consistent with ADEM, although multiple sclerosis remained a differential diagnosis. *Id.*

A few weeks later, on May 16, 2011, Elijah had a second MRI. *Id.* at \*5. This MRI showed a new small lesion on Elijah's brain. *Id.* The interpreting radiologist compared the second MRI with Elijah's previous MRI and concluded that the MRI's findings were consistent with ADEM. *Id.* But, after consulting with Dr. El-Zind, the radiologist also noted that "the possibility of multiple sclerosis is not excluded." *Id.* After another CSF study showed oligoclonal bands "suggesting multiple sclerosis," Elijah was discharged from the hospital on May 21, 2011, with a diagnosis of "[multiple sclerosis] flair." *Id.* at \*6.

On June 10, 2011, neurologist Dr. Mattson evaluated Elijah. *Id.* During this visit, Elijah reported the trouble with his left hand, but he did not tell Dr. Mattson about the past history of double vision. *Id.* Dr. Mattson considered Elijah to have ADEM; but noted that the presence of oligoclonal bands "increase[s] the risk that [the condition] will go on to be multiple sclerosis." *Id.*

On June 20, 2011, Elijah saw Dr. El-Zind again. *Id.* An MRI showed that "the number and distributions of the lesions appears stable" and that "there were 'three new foci of abnormal

enhancement.”” *Id.* The interpreting radiologist reported that the lesions are “nonspecific but consistent with the expected changes of evolving demyelinating lesions such as can be seen with [multiple sclerosis] or ADEM.” *Id.*

After experiencing headaches, body aches, and a stomach ache, Elijah returned to the hospital emergency room again on August 17, 2011. *Id.* A fourth MRI was performed on August 18, 2011, and showed more lesions. *Id.* The interpreting radiologist found the MRI results to be consistent with multiple sclerosis. *Id.*

On August 26, 2011, Elijah returned to see Dr. Mattson with a copy of his most recent MRI. *Id.* at \*7. At that time, Dr. Mattson stated that he felt “very comfortable that this has been declared as multiple sclerosis.” *Id.* On December 23, 2011, Dr. Mattson saw Elijah for a follow-up visit, and he concluded that Elijah had been suffering from pediatric onset multiple sclerosis of “approximately 8 months duration.” *Id.* Dr. Mattson continues to treat Elijah and with treatment, Elijah has not had any subsequent severe flares of multiple sclerosis. *Id.* at 7.

## **B. Procedural History**

The relevant procedural history is set forth in the special master’s decision. In short, on April 10, 2012, the prior petitioner in this matter, Tomika McLeod, filed a petition for vaccine compensation on behalf of Elijah under the Vaccine Act. *Id.* at \*1 n. 2. In her petition, Ms. McLeod alleged that Elijah suffered from ADEM and multiple sclerosis as the result of Tdap, meningococcal, and varicella booster vaccinations that Elijah received on April 20, 2011. *Id.* at \*1.

Following the submission of medical records and expert reports, the special master convened an entitlement hearing on January 9, 2014. *Id.* at \*9. During the hearing, Elijah and Dr. Mattson testified on behalf of petitioner, and the government’s medical expert, Dr. Sriram, also testified on behalf of respondent. *See generally* Transcript of Hearing, dated January 9, 2014. On January 10, 2014, the caption of this case was amended to add Jacqueline Hunt as the petitioner. *Id.* at \*1 n. 2. On February 23, 2015, the special master entered a decision denying petitioner’s request for compensation. *See generally* Dec.

On March 25, 2015, petitioner filed a motion for review of the special master's decision in this Court. *See generally* Pet. Mot. The Secretary of Health and Human Services filed a response to petitioner's motion for review on April 24, 2015. *See generally* Resp. Mot.

### **C. The Special Master's Decision**

On February 23, 2015, the special master issued a decision denying petitioner's claim for compensation under the Vaccine Act. *See generally* Dec. In the decision, the special master determined, as an initial matter, that the onset of Elijah's multiple sclerosis predated the vaccinations. *Id.* at \*10-12. Relying upon this Court's decision in *Paluck*, the special master then looked for evidence of multiple sclerosis before the vaccinations. *Id.* at \*10; *Paluck v. Sec'y of Health & Human Servs.*, 104 Fed. Cl. 457, 469 (2012) (remanding case), *rev'ing after remand*, 113 Fed. Cl. 210 (2013), *aff'd*, 786 F.3d 1373 (Fed. Cir. 2015). And so, the special master concluded that the case presented was one of alleged significant aggravation, rather than causation-in-fact. *Id.* at \*12.

In this regard, the special master found that Elijah experienced at least two symptoms that could indicate of a problem with his central nervous system prior to the vaccinations. First, in 2010, Elijah developed weakness in his dominant hand. Dec. at \*12. Second, Elijah experienced episodes of double vision beginning in February 2011. *Id.* Based upon this medical evidence, the special master determined that Elijah experienced clinical symptoms of multiple sclerosis before the April 20, 2011 vaccinations. *Id.* The special master also observed that Elijah's treating physician, Dr. Mattson, conceded on cross-examination that Elijah suffered from subclinical multiple sclerosis before the vaccinations. *Id.* And so, the special master concluded that petitioner's causation-in-fact claim was untenable given the finding of preexisting multiple sclerosis and that petitioner may only pursue her significant aggravation theory. *Id.* at \*14.

With respect to petitioner's significant aggravation claim, the special master similarly found that petitioner failed to meet her burden of proof. *Id.* at \*14-25. In particular, the special master found that petitioner's medical theory—that vaccines can aggravate multiple sclerosis—“is contrary to an unrebutted epidemiologic study on this precise question.” *Id.* at \*1. The special master also found that petitioner had not met her burden of proof to show how any of the specific vaccines that Elijah received can cause or significantly aggravate multiple sclerosis. *Id.* at \*18.

Specifically, the special master rejected as unpersuasive two medical theories put forward by petitioner to show a connection—*via* molecular mimicry or bystander activation—between multiple sclerosis and the relevant vaccines. *Id.* at \*15-18. In this regard, the special master noted that none of the medical literature relied upon by petitioner connected the relevant vaccines to multiple sclerosis. *See id.* at \*15. The special master also noted that one medical study submitted in the case, the Zorzon study, pertained to multiple sclerosis and the varicella vaccine. *Id.* at \*16. But, the special master accorded the Zorzon study no weight, because petitioner did not elicit any testimony regarding that study or address the study in her post-hearing briefs. *Id.* And so, the special master concluded that petitioner did not establish, by a preponderance of the evidence, that any of the vaccines Elijah received can cause, or significantly aggravate, multiple sclerosis. *Id.* at \*18.

Lastly, with respect to the timing of the onset of Elijah’s alleged injury, the special master also determined that the biologic process proposed by petitioner would take at least three days following the vaccinations. *Id.* at \*1. In this regard, the special master also found that this threshold has not been met in this case, because Elijah first exhibited symptoms one day after receiving the vaccinations. *Id.* And so, the special master concluded that petitioner failed to meet her burden of proof regarding the appropriate temporal interval for the onset of Elijah’s symptoms. *Id.* at 2.

Petitioner, alleging error, seeks review of the special master’s decision.

### **III. STANDARDS FOR DECISION**

#### **A. Standard Of Review**

The United States Court of Federal Claims has jurisdiction to review the record of the proceedings before a special master and, upon such review, may:

- (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master’s decision;
- (B) set aside any findings of fact or conclusions of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law; or
- (C) remand the petition to the special master for further action in accordance with the court’s direction.

42 U.S.C. § 300aa–12(e)(2).

The special master’s determinations of law are reviewed *de novo*. *Andreu ex rel. Andreu v. Sec’y of Dep’t of Health & Human Servs.*, 569 F.3d 1367, 1373 (Fed. Cir. 2009). The special master’s findings of fact are reviewed for clear error. *Id.*; *see also Broekelschen v. Sec’y of Health & Human Servs.*, 618 F.3d 1339, 1345 (Fed. Cir. 2010) (“We uphold the special master’s findings of fact unless they are arbitrary or capricious.”). In addition, a special master’s findings regarding the probative value of the evidence and the credibility of witnesses will not be disturbed so long as they are “supported by substantial evidence.” *Doe v. Sec’y of Health & Human Servs.*, 601 F.3d 1349, 1355 (Fed. Cir. 2010) (citing *Whitecotton ex rel. Whitecotton v. Sec’y of Health & Human Servs.*, 81 F.3d 1099, 1105 (Fed. Cir. 1996), *on remand from Shalala v. Whitecotton*, 514 U.S. 268 (1995)); *see also Porter v. Sec’y of Health & Human Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011) (providing the standard for an off-Table injury). This “level of deference is especially apt in a case in which the medical evidence of causation is in dispute.” *Hodges v. Sec’y of the Dep’t of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993).

## **B. Causation And Significant Aggravation**

Pursuant to the Vaccine Act, the Court shall award compensation if a petitioner proves, by a preponderance of the evidence, all of the elements set forth in 42 U.S.C. § 300aa–11(c)(1), unless there is a preponderance of evidence that the illness is due to factors unrelated to the administration of the vaccine. 42 U.S.C. § 300aa–13(a)(1). A petitioner can recover either by proving an injury listed on the Vaccine Injury Table (“Table”) or by proving causation-in-fact. *See* 42 U.S.C. §§ 300aa–11(c)(1)(C).

To establish a *prima facie* case when proceeding on a causation-in-fact theory, as petitioner seeks to do in this matter, a petitioner must “prove, by a preponderance of the evidence, that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” *Shyface v. Sec’y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). “[T]o show that the vaccine was a substantial factor in bringing about the injury, the petitioner must show ‘a medical theory causally connecting the vaccination and the injury.’” *Id.* at 1352–53 (quoting *Grant v. Sec’y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992) (*per curiam*)). In other words, “[t]here must be a ‘logical sequence of cause and effect showing that the vaccination was the reason for the injury,’” *id.* at 1353 (quoting

*Grant*, 956 F.2d at 1148), and “[t]his ‘logical sequence of cause and effect’ must be supported by a sound and reliable medical or scientific explanation.” *Knudsen ex rel. Knudsen v. Sec’y of the Dep’t of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994) (citing *Jay v. Sec’y of Dep’t of Health & Human Servs.*, 998 F.2d 979, 984 (Fed. Cir. 1993)); *see also* 42 U.S.C. § 300aa–13(a)(1) (“The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.”). However, medical or scientific certainty is not required. *Knudsen*, 35 F.3d at 548–49.

In *Althen*, the Federal Circuit set forth three elements that a petitioner must provide to prove causation-in-fact:

(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

*Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). All three prongs “must cumulatively show that the vaccination was a ‘but-for’ cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm.” *Pafford v. Sec’y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006).

With respect to a significant aggravation claim, the Vaccine Act defines significant aggravation as “any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.” 42 U.S.C. § 300aa–33(4). In off-Table cases, like here, additional proof is necessary for a petitioner to prevail on a significant aggravation claim. 42 U.S.C. § 300aa-11(c)(1)(C).

In this regard, the Federal Circuit has held that to establish a *prima facie* case for the significant aggravation of an off-Table injury, a petitioner must show by preponderant proof:

(1) the person’s condition prior to administration of the vaccine, (2) the person’s current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person’s current condition constitutes a “significant aggravation” of the person’s condition prior to the vaccination, (4) a medical theory causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) . . . a proximate temporal relationship between the vaccination and the significant aggravation.



*W.C. v. Sec’y of Health & Human Servs.*, 704 F.3d 1352, 1357 (Fed. Cir. 2013) (quoting *Loving ex. rel. Loving v. Sec’y of Health & Human Servs.*, 86 Fed. Cl. 135, 144 (2009)). The United States Court of Appeals for the Federal Circuit further makes clear that “a petitioner in an off-[T]able case must show the vaccine actually caused the significant aggravation—not just that, accepting petitioner’s medical theory as sound, the person’s condition worsened within a medically-acceptable time frame.” *Id.*

If a petitioner establishes a prima facie case, the burden shifts to the respondent to show, by a preponderance of the evidence, that the injury was caused by a factor unrelated to the vaccine. *See* 42 U.S.C. § 300aa-13(a)(1)(B); *Shalala*, 514 U.S. at 270–71. But, regardless of whether the burden of proof ever shifts to the respondent, the special master may consider the evidence presented by the respondent in determining whether the petitioner has established a prima facie case. *See Stone v. Sec’y of Health & Human Servs.*, 676 F.3d 1373, 1379 (Fed. Cir. 2012) (“[E]vidence of other possible sources of injury can be relevant not only to the ‘factors unrelated’ defense, but also to whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question.”); *de Bazan v. Sec’y of Health & Human Servs.*, 539 F.3d 1347, 1353 (Fed. Cir. 2008) (“The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the petitioner’s evidence on a requisite element of the petitioner’s case[-]in-chief.”).

#### IV. LEGAL ANALYSIS

The petitioner enumerates five objections to the special master’s decision. First, petitioner argues that the special master erred by considering evidence of preexisting multiple sclerosis before considering her causation-in-fact claim. Pet. Mot. at 2-5. Second, petitioner also argues that the special master abused his discretion by failing to consider probative evidence supporting her causation-in-fact claim. *Id.* at 5-6. Third, petitioner contends that the special master’s determination that Elijah suffered from multiple sclerosis prior to the vaccinations was arbitrary and capricious. Pet. Mot. at 6-9. Fourth, petitioner contends that the special master erred in analyzing her significant aggravation claim, by imposing a heightened burden of proof for the medical theory, timing, and logical sequencing prongs under *Althen* and *Loving*. Pet. Mot. at 9-15, 18-21. Lastly, petitioner argues that the special master erred in determining the

medically-appropriate time period for the onset of Elijah's symptoms after the vaccinations. Pet. Mot. at 15-18.

For the reasons discussed below, the record evidence shows that the special master committed several errors in analyzing petitioner's claim. But, the special master, nonetheless, correctly determined that petitioner had not established that she is entitled to compensation under the Vaccine Act. And so, the Court sustains the decision of the special master.

#### **A. The Special Master Erred In Analyzing Petitioner's Causation Claim**

##### **1. The Special Master Erred In Making A Preliminary Diagnosis**

As an initial matter, petitioner correctly argues that the special master erred in making a preliminary determination regarding the pre-vaccination status of Elijah's health, before applying the analysis required under *Althen*. Pet. Mot. at 2-3; *see also Althen*, 418 F.3d at 1278. At the outset of this case, the special master determined that the first matter to be resolved was the status of Elijah's health prior to the vaccines. Dec. at \*10. And so, the special master determined that Elijah "manifested symptoms of multiple sclerosis before the vaccination[s]." *Id.*

The special master erred in making this preliminary determination. In *Broekelschen*, the United States Court of Appeals for the Federal Circuit held that, when there is disagreement about the very nature of a petitioner's injury, a special master does not err by preliminarily determining which of two possible and different medical diagnoses was correct. 618 F.3d at 1345-46. Similarly, in *Lombardi v. Sec'y of Health and Human Servs.*, when the petitioner in that case failed to show "the very existence of any specific injury," the United States Court of Appeals for the Federal Circuit held that the special master could first determine what injury, if any, the petitioner had suffered after receiving the vaccine. 656 F.3d 1343, 1353 (Fed. Cir. 2011). The *Lombardi* and *Broekelschen* cases are, however, distinguishable from this matter.

Here, there is no disagreement about the nature of Elijah's injuries. Dec. at \*4-10, \*17. In fact, both parties agree that Elijah has experienced neurological symptoms involving the central nervous system. Pet. Mot. at 8-9; Resp. Mot. at 2-5. Moreover, while petitioner alleges that the vaccines initially caused ADEM, she also acknowledges that "ADEM is part of the spectrum of inflammatory demyelinating diseases that encompass ADEM and multiple

sclerosis.” *Id.* at 3. And so, given the general agreement among the parties about the nature of Elijah’s injury, there was no legal or factual basis under either *Broekelschen* or *Lombardi* for the special master to determine, as a preliminary matter, that Elijah suffered from multiple sclerosis. *Broekelschen*, 618 F.3d at 1345-46; *Lombardi*, 656 F.3d 1353.

The special master similarly erred in determining that Elijah had multiple sclerosis prior to the vaccinations, before fully analyzing petitioner’s causation-in-fact claim. Relying upon this Court’s decision in *Paluck*, the special master looked for evidence of multiple sclerosis that may have been present before the vaccinations at the outset of the case. *See Paluck*, 104 Fed. Cl. at 469 (remanding to special master), *rev’ing decision after remand*, 113 Fed. Cl. 210, 225 (2013), *aff’d*, 786 F.3d 1373 (Fed. Cir. 2015); Dec. at \*10. In doing so, the special master found evidence of preexisting multiple sclerosis. Dec. at \*10. And so, he concluded that “[t]he legal consequence of finding that Elijah suffered clinical symptoms of multiple sclerosis and had (undetected) laboratory evidence of multiple sclerosis means that [petitioner] may pursue her significant aggravation theory only.” *Id.* at \*12.

The special master’s reliance upon *Paluck* to bypass the analysis required under *Althen* in reaching his determination is misplaced. In *Paluck*, this Court observed that, if symptoms of an illness were manifest pre-vaccination, the case involves a significant aggravation claim. *Paluck*, 104 Fed. Cl. at 469. But, the Court does not read the *Paluck* decision to hold that a special master may completely bypass the framework set forth in *Althen* in determining whether such a preexisting injury exists. *See id.* at 470-83. Rather, in *Paluck*, the Court observed that the special master in that case correctly conducted the analysis under *Althen* in considering the petitioner’s claims. *Id.* at 469. Because the special master did not fully analyze petitioner’s causation-in-fact claim under *Althen* before turning to the question of whether the vaccines caused a significant aggravation of Elijah’s injury, he erred in analyzing petitioner’s causation-in-fact claim. *Id.*; *Althen*, 418 F.3d. at 1278.

## **2. The Special Master Abused His Discretion By Failing To Consider Evidence Supporting Petitioner’s Causation-In-Fact Claim**

The special master also erred by failing to consider probative evidence supporting petitioner’s causation-in-fact claim. In her petition for review, petitioner alleges that the special master abused his discretion by failing to consider probative evidence and testimony supporting

her claim that the vaccinations caused Elijah to develop ADEM and later multiple sclerosis. Pet. Mot. at 5-6. The Court agrees.

This Court has long recognized that special masters have broad authority in building a record for decision in vaccine cases and enjoy “flexible and informal standards of admissibility of evidence.” *Davis v. Sec’y of Health & Human Servs.*, 94 Fed. Cl. 53, 65 (2010), *aff’d in part, rev’d on other grounds*, 420 F. App’x 973 (Fed. Cir. 2011) (quoting 42 U.S.C. § 300aa–12(d)(2)(B)). However, “that authority may not be used in a way that deprives a party of procedural rights provided by the Vaccine Act and the Vaccine Rules.” *Simanski v. Sec’y of Health & Human Servs.*, 671 F.3d 1368, 1385 (Fed. Cir. 2012). In this regard, Vaccine Rule 8(b)(1) directs the special master to consider “all relevant and reliable evidence.” Vaccine Rule 8(b)(1); *see also* 42 U.S.C. § 300aa–13(b)(1) (The special master shall consider certain medical information “in addition to all other relevant medical and scientific evidence.”); *cf.* Fed. R. Evid. 402 (“Irrelevant evidence is not admissible.”). And so, while “the special master need not address every snippet of evidence adduced in the case, . . . he cannot dismiss so much contrary evidence that it appears that he ‘simply failed to consider genuinely the evidentiary record before him.’” *Paluck*, 104 Fed. Cl. at 467 (quoting *Campbell v. Sec’y of Health & Human Servs.*, 97 Fed. Cl. 650, 668 (2011)) (citation omitted).

The record also shows that the special master did not fully consider evidence in support of petitioner’s causation-in-fact claim that the vaccinations caused post-vaccinal ADEM. During the proceedings before the special master, petitioner submitted medical records showing that six treating physicians diagnosed Elijah with post-vaccinal ADEM. *See* Dec. at \*6, \*8; Ex. 10 at 3, 5-9; Ex. 12 at 252-53. Petitioner also submitted six pieces of medical literature to support her claim that vaccines can trigger ADEM. *See generally* Ex. 29; Ex. 30; Ex. 31; Ex. 36; Ex. 37. In particular, one piece of medical literature, the Menge article, refers to the pertussis vaccine—one of the vaccines that Elijah received—as being associated with ADEM. Tr. 68:17-20; Ex. 31 at 2. Another medical article, the Hartung article, also states that ADEM is known to follow the diphtheria-tetanus-pertussis (“DTaP”) vaccine, which Elijah also received. Ex. 34 at 2.

By failing to consider this evidence, the special master ignored probative evidence in support of petitioner’s causation-in-fact claim. As discussed above, while the special master need not address all evidence, he cannot simply fail to consider the full evidentiary record in the

case. *See Paluck*, 104 Fed. Cl. at 467. And so, the special master abused his discretion in failing to fully consider evidence to support petitioner’s causation-in-fact claim.

**B. The Special Master’s Errors Are Harmless Because Petitioner Has Not Proven Her Causation-In-Fact Claim**

While the special master committed several errors in assessing petitioner’s causation-in-fact claim, those errors are, nonetheless, harmless because petitioner has not proven her claim. In *Althen*, the Federal Circuit set forth a three-part test to prove causation-in-fact, requiring a petitioner to provide:

(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

*Althen*, 418 F.3d at 1278. All three prongs “must cumulatively show that the vaccination was a ‘but-for’ cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm.” *Pafford*, 451 F.3d at 1355. For the reasons discussed below, the *Althen* prongs cumulatively weigh against petitioner’s causation-in-fact claim here.

**1. Petitioner Has Not Proven A Logical Sequence**

First, petitioner fails to show a logical sequence of cause and effect, showing that the vaccines were the reason for Elijah’s illness. *Althen*, 418 F.3d at 1278; *Shyface*, 165 F.3d at 1353. To establish a prima facie case on a causation-in-fact theory, petitioner must “prove, by a preponderance of the evidence, that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” *Shyface*, 165 F.3d at 1352. And so, “[t]here must be a ‘logical sequence of cause and effect showing that the vaccination was the reason for the injury,’” *id.* at 1353 (*quoting Grant*, 956 F.2d at 1148), and “[t]his ‘logical sequence of cause and effect’ must be supported by a sound and reliable medical or scientific explanation.” *Knudsen*, 35 F.3d at 548 (*quoting Jay*, 998 F.2d at 984); *see also* 42 U.S.C. § 300aa–13(a)(1) (“The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.”).

In this case, there is ample evidence in the record—much of it undisputed—that Elijah suffered from multiple sclerosis prior to the vaccinations. As a result, the substantial weight of the evidence shows that the vaccines did not cause his illness.

In this regard, the record evidence shows that Elijah developed weakness in his dominant hand and experienced episodes of double vision prior to the vaccinations. Dec. at \*12. Elijah also testified that he experienced numbness in his arm and had episodes of double vision prior to the vaccinations—both recognized symptoms of multiple sclerosis. Tr. 105:15-20, 106:12-18, 260:2-23. During his testimony before the special master, Elijah’s treating physician, Dr. Mattson, also acknowledged that these two symptoms can be indications of multiple sclerosis. Tr. 105:15-20, 106:12-18; *see also* Pet. Mot. at 8.

The record also shows that a medical test conducted shortly after Elijah received the vaccines indicates that the onset of Elijah’s multiple sclerosis occurred before the vaccinations. Specifically, a CSF study conducted in May 2011 showed oligoclonal bands in Elijah’s spinal fluid, “suggesting multiple sclerosis.” Dec. at \*5. Both medical experts in this case, Dr. Mattson and Dr. Sriram, agree that the oligoclonal bands in Elijah’s spinal fluid were likely present before the administration of vaccines. Tr. 84:3-4, 195:11-15. Most likely for this reason, Dr. Mattson also acknowledged during his testimony before the special master that Elijah suffered from subclinical multiple sclerosis before the vaccinations. Tr. 119:13-16.

While petitioner correctly maintains that there is evidence in the record showing that several physicians diagnosed Elijah with post-vaccinal ADEM, a finding that the onset of Elijah’s injuries occurred after the vaccinations is simply contradicted by the substantial weight of all of the evidence.<sup>2</sup> Pet. Mot. at 6-7. In fact, while petitioner disagrees that the neurological

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<sup>2</sup> On April 23, 2011, Dr. El-Zind reported that Elijah had “possible acute disseminating encephalomyelitis with [a] post-immunization reaction.” Ex. 5 at 12. Radiologist Dr. Allison Lamont’s impression of Elijah’s April 23, 2011, MRI stated that it was “likely related to acute disseminated encephalomyelitis (ADEM), seen in post vaccination settings. A demyelinating process such as multiple sclerosis is felt to be much less likely.” Ex. 5 at 350. Radiologist Dr. Pedro Miro’s interpretation of Elijah’s second MRI taken on May 16, 2011, stated that “[t]he findings are consistent with the patient’s repeated history of acute disseminated encephalomyelitis (ADEM).” Ex. 9 at 232. Dr. Lisa Smith, a neurologist, said, “[t]he etiology for this presentation most closely correlates with [Elijah] receiving his vaccinations prior to the onset of the disease.” Ex. 10 at 7. Dr. Mattson noted on June 10, 2011, “[Elijah] is certainly to stay away from vaccinations in the future because that was very likely the triggering event for his multifocal

symptoms Elijah experienced in 2010 and early 2011 were caused by multiple sclerosis, she, nonetheless, acknowledges that these symptoms occurred before the vaccinations. Pet. Mot. at 17. Petitioner also fails to explain why these symptoms should not be attributed to Elijah's multiple sclerosis. *Id.* at 8-9. And so, petitioner fails to show, by a preponderance of the evidence, a logical sequence of cause and effect connecting any one of the vaccines that Elijah received to his illness.

In addition, petitioner's other objections to the special master's finding of preexisting multiple sclerosis are misplaced. In her motion, petitioner argues that the special master's determination that Elijah suffered from multiple sclerosis prior to the vaccinations was arbitrary and capricious. Pet. Mot. at 6-9; *see also* Dec. at \*9. But, as discussed above, the evidence in the record supports the special master's determination that "Elijah suffered clinical symptoms of multiple sclerosis" prior to the vaccinations. Dec. at \*12.

Given this evidence, the special master reasonably concluded that the onset of Elijah's injury occurred prior to the vaccinations. The Court will not set aside the special master's finding. *Broekelschen*, 618 F.3d at 1345 ("We uphold the special master's findings of fact unless they are arbitrary or capricious.") (citing *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1324 (Fed. Cir. 2006)).

Petitioner also incorrectly argues that the special master erred by considering evidence presented by the government to show that the onset of multiple sclerosis occurred prior to the vaccinations during the presentation of her causation-in-fact claim. Pet. Mot. at 2-3. In this regard, it is well established that evidence of other possible sources of an illness can also be relevant to a petitioner's prima facie case. *See Stone*, 676 F.3d at 1379. For this reason, this Court has recognized that a special master may consider the evidence presented by the respondent in determining whether the petitioner has established a prima facie case, regardless of whether the burden of proof ever shifts to the respondent under the Vaccine Act. *Id.* ("[E]vidence of other possible sources of injury can be relevant not only to the 'factors

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demyelination." Ex. 10 at 3. Dr. Madden's interpretation of Elijah's June 21, 2011, MRI included the comment that "these lesions are nonspecific but consistent with the expected changes of evolving demyelinating lesions such as can be seen with [multiple sclerosis] or ADEM. There are no new lesions and this may be more consistent with ADEM . . . ." Ex. 12 at 251.

unrelated' defense, but also to whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question.”); *de Bazan*, 539 F.3d at 1353 (“The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the petitioner’s evidence on a requisite element of the petitioner’s case[-]in-chief.”).

Here, the record shows that the government presented evidence of preexisting multiple sclerosis to rebut the petitioner’s prima facie case. *See* Dec. at \*11; Ex. A at 3; Respondent’s Report 10-11, Aug. 29, 2012. Such evidence is certainly relevant to the question of whether petitioner has proven her prima facie case that vaccines caused Elijah’s injury. And so, the special master properly considered this evidence within the context of assessing petitioner’s causation-in-fact claim. *See Stone*, 676 F.3d at 1379; *de Bazan*, 539 F.3d at 1353.

In sum, the substantial weight of the record evidence supports the special master’s finding that the onset of Elijah’s multiple sclerosis occurred before the vaccinations. Given this, petitioner has not satisfied the logical sequence prong under *Althen*.

## **2. Petitioner Has Not Satisfied The Timing Prong**

For these same reasons, petitioner also fails to establish a proximate temporal relationship between vaccinations and the onset of Elijah’s injury. In this regard, this Court has recognized that, if symptoms arise too soon to be caused by a vaccine, “the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked.” *de Bazan*, 539 F.3d at 1352. As discussed above, the record evidence here shows that Elijah experienced symptoms of multiple sclerosis in the fall of 2010 and again in February 2011, many months before the vaccinations. Dec. at \*2. Petitioner does not dispute that these symptoms occurred prior to the vaccinations. Pet. Mot. at 8-9. Nor does she eliminate any alternative causes for these symptoms. *Id*; *see also de Bazan*, 539 F.3d at 1353 (finding that when symptoms arise too soon to be caused by a vaccine, they must have an alternative cause and that it does not raise the burden of proof to require petitioner to eliminate those alternative causes). And so, petitioner simply has not proven by a preponderance of the evidence that a temporal relationship exists between the vaccinations and the onset of Elijah’s injury in this case. *de Bazan*, 539 F.3d at 1352.



### **3. Petitioner Has Not Satisfied The Medical Theory Prong**

Because petitioner cannot satisfy the logical sequence or timing prongs under *Althen*, it is not necessary to analyze petitioner's causation-in-fact claim under the medical theory prong. *See W.C.*, 704 F.3d at 1358 (finding that "[t]he lack of a logical sequence of cause and effect, and the lack of a 'medically-acceptable temporal relationship' between the vaccination and disease onset" can prevent petitioner from establishing a causation-in-fact claim). Nonetheless, as discussed below, petitioner also fails to meet her burden under the medical theory prong, because she has not established a link between any of the vaccines that Elijah received and his injury.

Because the three *Althen* prongs for a causation-in-fact off-Table case do not cumulatively show that the vaccinations at issue here were a 'but-for' cause of Elijah's injury, petitioner has not proven her causation-in-fact claim. And so, as the special master concluded during the proceedings below, the Court concludes that the case presented here is one of possible significant aggravation.

### **C. Petitioner Has Not Proven Her Significant Aggravation Claim**

The record evidence also shows that petitioner has not proven her significant aggravation claim. In her motion for review, petitioner alleges that the special master committed reversible error by imposing a heightened burden of proof when analyzing her significant aggravation claim under the medical theory, logical sequence, and temporal relationship prongs set forth in *Loving* and *Althen*. Pet. Mot. at 9-15, 18-21. For the reasons discussed below, the special master erred in applying the timing and logical sequence prongs under *Loving* and *Althen*, but correctly concluded that petitioner had not proven her significant aggravation claim.

#### **1. The Special Master Properly Analyzed The Medical Theory Prong**

As an initial matter, petitioner incorrectly argues that the special master held her to a heightened burden of proof under the medical theory prong of *Althen* and *Loving*. Pet.'s Mot. at 10. As established above, pursuant to the Vaccine Act, a "significant aggravation" involves "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." 42 U.S.C. § 300aa-33(4). In off-Table cases, like here, additional proof is necessary for a petitioner to prevail on a significant aggravation claim. And so, to prove a prima facie case for the significant aggravation of an off-Table injury, a petitioner must provide:

(1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a "significant aggravation" of the person's condition prior to the vaccination, (4) a medical theory causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) . . . a proximate temporal relationship between the vaccination and the significant aggravation.

*W.C.*, 704 F.3d at 1357 (quoting *Loving*, 86 Fed. Cl. at 144).

In addition, the Vaccine Act requires that petitioners prove causation and significant aggravation claims "by a preponderance of the evidence," which can be satisfied "by medical records or by medical opinion." 42 U.S.C. § 300aa-13(a)(1). Moreover, the United States Court of Appeals for the Federal Circuit has recognized that a petitioner's claim should not be barred due to a lack of medical literature supporting that theory. *Andreu*, 569 F.3d at 1378 ("Requiring 'epidemiologic studies . . . or general acceptance in the scientific or medical communities . . . impermissibly raises a claimant's burden under the Vaccine Act and hinders the system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants.'" (quoting *Capizzano*, 440 F.3d at 1325-26)). Nonetheless, a petitioner must do more than demonstrate a "plausible" or "possible" causal link between the vaccination and the injury. *Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 (Fed. Cir. 2010). "[N]either a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation." *Althen*, 418 F.3d at 1278. And so, "a petitioner in an off-[T]able case must show the vaccine *actually caused the significant aggravation*—not just that, accepting petitioner's medical theory as sound, the person's condition worsened within a medically-acceptable time frame. *W.C.*, 704 F.3d at 1357 (emphasis supplied).

In *W.C. v. Sec'y of Health & Human Servs.*, the United States Court of Appeals for the Federal Circuit held that a special master correctly required the petitioner in that case to provide specific evidence showing that the vaccine at issue in that case caused a significant aggravation of the petitioner's multiple sclerosis through the process of molecular mimicry. 704 F.3d at 1360. In that case, the petitioner argued that the influenza vaccine significantly aggravated his

multiple sclerosis. *Id.* at 1355. But, the petitioner did not show that the particular parts of the influenza virus that had been shown to be linked to multiple sclerosis were actually present in the vaccine that he received. *Id.* at 1360-61. For this reason, the United States Court of Appeals for the Federal Circuit concluded that the petitioner failed to satisfy the medical theory prong. *Id.* at 1361. The United States Court of Appeals for the Federal Circuit's decision in *W.C.* is instructive here.

In this matter, the special master required petitioner to establish that at least one of the vaccines Elijah received was capable of—through either molecular mimicry or bystander activation—causing significant aggravation of multiple sclerosis. Dec. at \*15. The United States Court of Appeals for the Federal Circuit's holding in *W.C.* makes clear that the special master properly applied the standard in evaluating petitioner's medical theory. *Id.* And so, petitioner has not been held to a heightened burden of proof under the medical theory prong in this case.

The special master also correctly determined that petitioner did not satisfy the medical theory prong, because she put forward no evidence to connect any of the vaccines that Elijah received to multiple sclerosis. In this regard, the record evidence shows that petitioner failed to put forward any medical literature or testimony to connect the Tdap, varicella and meningococcal vaccines with multiple sclerosis. *Id.* at \*15-18. In contrast, the government put forward two medical studies—the Farez and Confavreux studies—that refute any connection between the varicella vaccine (Farez study) or the Tdap vaccine (Confavreux and Farez studies) and multiple sclerosis. *Id.* at \*15. Moreover, while another study—the Zorzon study—finds a connection between the varicella vaccine and multiple sclerosis, petitioner did not elicit testimony on this study to support her significant aggravation claim. *Id.* at \*16. And so, the special master afforded this study no weight.<sup>3</sup> *Id.*

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<sup>3</sup> Because the Court grants deference to the finder of fact with respect to the probative value of evidence, the Court will not reconsider the special master's determination regarding the probative value of the Zorzon study. *Doe*, 601 F.3d at 1356.

Given the lack of evidence in the record to connect any of the relevant vaccines to multiple sclerosis, the special master reasonably determined that petitioner did not satisfy the medical theory prong in this case. The Court will not disturb the finding of the special master.<sup>4</sup>

Because petitioner has not met her burden under the medical theory prong for the significant aggravation claim, the Court need not address whether she satisfies the other prongs under *Althen* and *Loving*. *Veryzer v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 344, 355-56 (2011), *aff'd sub nom. Veryzer v. United States*, 475 F. App'x 765 (Fed. Cir. 2012) (“Absent [a legally probable medical] theory, a logical sequence of cause and effect showing that receipt of the . . . vaccine led to petitioner's condition could not be shown. . . . [T]he record did not establish a plausible medical theory causally connecting the vaccine and the alleged injuries. Absent such a showing, a temporal association cannot be demonstrated.”). Nonetheless, the Court agrees with petitioner that the special master erred in analyzing her significant aggravation claim under the timing and logical sequence prongs. Pet. Mot. at 14-15. And so, the Court briefly addresses these issues.

## **2. The Special Master Erred In Analyzing The Timing Prong**

With respect to the timing prong, the record evidence shows that the special master erred in setting a three-day time limit following the vaccinations as the medically acceptable interval before the onset of Elijah's symptoms. Dec. at \*22-23. Under the timing prong, the petitioner must demonstrate by a preponderance of the evidence that the injury or significant aggravation occurred “within a medically acceptable interval following his vaccinations.” *Paluck*, 786 F.3d

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<sup>4</sup> It is important also to note that the record is similarly devoid of evidence connecting the relevant vaccines to ADEM. As discussed above, the Court finds that the special master abused his discretion by failing to fully consider evidence put forward by petitioner to show that the vaccines caused ADEM. But, while the record shows that petitioner put forward several medical studies to support her medical theory that the vaccines caused ADEM, two of those studies do not connect any of the relevant vaccines to ADEM. *See, e.g.*, Tr. 65:17-66:4 (Johnson article connecting the rabies vaccines to ADEM through molecular mimicry), 69:2-14 (Tselis article addressing the theories of molecular mimicry and bystander activation as they relate to ADEM); Exs. 29 at 4, 37 at 6-7. Another medical study—the Hartung article—states that ADEM is known to follow the DTaP vaccine. Ex. 34 at 2. In addition, a fourth medical study—the Menge study—states that ADEM can occur after the pertussis vaccination in .9 of 100,000 patients. Tr. 68:5-69:1; Ex. 31 at 2. But, the testimony from petitioner's own medical expert mitigates the probative value of this study, because Dr. Mattson testified that the Tdap vaccine probably did not cause Elijah's injury. Tr. 60:12-15; 120:5-13. (Dr. Mattson testified that the varicella vaccine was the most likely cause of Elijah's injuries because it is a live, attenuated vaccine unlike the Tdap vaccine.)

at 1380. “[T]he proximate temporal relationship prong requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder’s etiology, it is medically acceptable to infer causation-in-fact.” *de Bazan*, 539 F.3d at 1352.

In this case, the special master concluded that “the evidence suggests that an immune-mediated reaction in a person with an intact central nervous system takes at least five days. [But] [b]ecause Elijah’s central nervous system already contained some antibodies . . . he [may have] respond[ed] more rapidly.” Dec. at \*22. And so, the special master concluded that “a generous estimate in [petitioner’s] favor is that the interval might be as few as three days.” *Id.*

Petitioner, however, presented expert testimony and medical literature to support her position that a medically appropriate time period for the onset of Elijah’s symptoms is 2 to 21 days after the vaccinations. *See* Tr. 64:25-65:16 (Scott study finding onset of ADEM symptoms after the smallpox vaccine within 2 to 18 days); Ex. 35 at 2-3 (Tenenbaum study finding 2 to 28 days is an appropriate interval to expect the onset of symptoms after infection); Ex. 36 at 5 (providing age-based incubation periods for the smallpox vaccine).<sup>5</sup> The medical literature put forward by petitioner provides ample support for the view that the onset of Elijah’s symptoms could have occurred as early as two days after he received the vaccinations. *See* Tr. 64:25-65:16; Ex. 35 at 2-3; Ex. 36 at 5. Given this probative evidence, the special master’s finding of a medically acceptable interval of no less than three days is not supported by the substantial record evidence. And so, this finding should be set aside.

The special master’s factual finding that Elijah’s symptoms occurred one day after he received the vaccinations is similarly contradicted by the record evidence. Dec. at \*23. The record evidence shows that Elijah was sent home by the emergency room medical staff after being diagnosed with a localized reaction to the vaccines on April 21, 2011. Dec. at \*3; Ex. 4 at 3. Rather, it was Elijah’s “stroke-like” symptoms which manifested on April 22, 2011, the second day after the vaccinations, that prompted his hospitalization and suggest the onset of more serious neurological symptoms. *See* Dec. at \*5; *see generally* Ex. 5. And so, the special

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<sup>5</sup> The special master discredited the Scott article because the data concerned infants, Dec. at \*19, and found the Tenenbaum article’s authority limited because neither expert witness was asked about the article during his testimony. *Id.*

master's factual determination that the onset of symptoms occurred within one day of the vaccinations is similarly unsupported by the substantial record evidence and should be set aside.

### **3. The Special Master Erred In Analyzing The Logical Sequence Prong**

Petitioner also correctly argues that the special master erred in his analysis of the logical sequence prong, by discounting the medical opinion of Elijah's treating physician, Dr. Mattson, with regard to whether the vaccines caused a significant aggravation of Elijah's injury. Pet. Mot. at 18-21. In his decision, the special master determined that "the factual bases for deferring to Dr. Mattson simply because he treated Elijah appear to be absent," because there is no understanding within the medical community about what causes multiple sclerosis and ADEM. Dec. at \*23. Given the general lack of understanding about the causes of these diseases, the special master also questioned "how . . . a treating doctor [could] offer a reliable opinion about whether a vaccination contributed to the disease's course." *Id.* at \*24. And so, the special master concluded that, "[t]he admitted lack of knowledge about the causes of multiple sclerosis lies at the heart of the finding that Dr. Mattson was not persuasive in opining that vaccinations can worsen multiple sclerosis." *Id.* The Court disagrees.

This Court recognizes that "treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect shows that the vaccination was the reason for the injury." *Andreu*, 569 F.3d at 1375 (citing *Capizzano*, 440 F.3d at 1326) (alteration in original). In this regard, the record shows Dr. Mattson has detailed, first-hand, knowledge about Elijah's medical history and the status of Elijah's health since the vaccinations. Dec. at \*6-11. The record evidence also shows that, as a professor of neurology at the Indiana University School of Medicine and the director of the university's Multiple Sclerosis Center, Dr. Mattson has extensive expertise and experience in diagnosing and treating multiple sclerosis. Tr. at 9-12. The fact that there is uncertainty within the medical community about the precise cause of multiple sclerosis does not alter these salient facts regarding his experience and knowledge of Elijah's medical condition. And so, while the special master may "determine whether the testimony has a reliable basis in the knowledge and experience of the [relevant discipline]," *Terran ex rel. Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)

(citation omitted) (brackets in original), he should not have discounted the opinion of petitioner's medical expert because of an uncertainty about the cause of multiple sclerosis.<sup>6</sup>

## V. CONCLUSION

In sum, petitioner presents a sympathetic and difficult case. There is no dispute that Elijah has multiple sclerosis. The record evidence also supports a finding that the onset of Elijah's multiple sclerosis occurred prior to the time that he received the Tdap, varicella, and meningococcal vaccines on April 20 2011. And so, petitioner has not proven, by a preponderance of the evidence, that any of these vaccines were the "but for" cause of Elijah's injury.

Nonetheless, there is ample evidence in the record to suggest that Elijah's medical condition worsened, significantly, two days after he received these vaccinations. Petitioner maintains that the vaccines caused this worsening condition and in doing so, she need not prove her claim to a medical certainty. But petitioner must, nonetheless, show that the vaccines actually caused the significant aggravation of Elijah's injury—not just that, accepting the medical theory as sound, that Elijah's condition worsened within a medically-acceptable time frame. *W.C.*, 704 F.3d at 1357. Petitioner has simply not met this burden here. And so, she has not established an entitlement to any compensation under the Vaccine Act.

For the foregoing reasons, the Court **DENIES** petitioner's motion for review and **SUSTAINS** the decision of the special master.

The Clerk is directed to enter judgment accordingly.

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<sup>6</sup> Lastly, while the Court need not reach this issue to resolve this matter, petitioner appears to satisfy the remaining *Loving* factors for a significant aggravation claim. See *W.C.*, 704 F.3d at 1357 (quoting *Loving*, 86 Fed. Cl. at 144) (holding that to prove a significant aggravation claim a petitioner must show in addition to the *Althen* factors, (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a "significant aggravation" of the person's condition prior to the vaccination.) As discussed above, the record evidence shows that Elijah's medical condition significantly deteriorated two days after receiving the vaccines. Dec. at \*3-4. The record evidence also suggests that Elijah's post-vaccination health status was significantly worse than his condition prior to the vaccinations. See *id.* In addition, there is no dispute that Elijah's current diagnosis is multiple sclerosis. *Id.* at \*1. And so, the evidence suggests that Elijah's condition worsened significantly two days after he received the vaccines and in the months following.

Each party to bear their own costs.

Some of the information contained in this Memorandum Opinion and Order may be considered privileged, confidential, or sensitive personally-identifiable information that should be protected from disclosure. Accordingly, this Memorandum Opinion and Order shall be **FILED UNDER SEAL**. The parties shall review the Memorandum Opinion and Order to determine whether, in their view, any information should be redacted prior to publication. The parties shall also **FILE**, by **Friday, August 28, 2015**, a joint status report identifying the information, if any, that they contend should be redacted, together with an explanation of the basis for each proposed redaction.

**IT IS SO ORDERED.**

s/ Lydia Kay Griggsby  
LYDIA KAY GRIGGSBY  
Judge